

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE: NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCT LIABILITY
LITIGATION

This document relates only to:

MDL No. 02419

Docket No. 1:13-md-2419-RWZ

Handy No. 1:14-cv-14019-RWZ

**PLAINTIFFS' SUPPLEMENTAL BRIEFING IN OPPOSITION TO BOX HILL
DEFENDANTS' PARTIAL MOTION FOR SUMMARY JUDGMENT ON PUNITIVE
DAMAGES**

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Notice: During the January 25, 2018 hearing regarding Box Hill Surgery Center, L.L.C.'s, Ritu T. Bhambhani, M.D.'s, and Ritu T. Bhambhani, M.D., L.L.C.'s (collectively "Box Hill Defendants," "Box Hill," or "Defendants") motion for summary judgment (Dkt. No. 3511), the Court granted Plaintiffs leave to file an additional 10 pages concerning issues related Plaintiffs' punitive damages claim. *See* Dkt. No. 3517.

I. INTRODUCTION

Punitive damages are justified in this action on two bases.

First, Plaintiffs are entitled to punitive damages under Maryland law on their medical negligence and informed consent claims because of Dr. Bhambhani's role in illegally obtaining NECC's preservative free MPA steroids for the Box Hill Surgical Center through completing and signing bogus prescriptions submitted to NECC via fax.¹ As describe more thoroughly in Plaintiffs' principle opposition brief, Dr. Bhambhani used Box Hill's past patient names to fill out NECC prescription order forms, which are the equivalent of the family doctor's prescription pad. The forms were faxed to NECC, then dispensed and sent by Box Hill via Federal Express—five 5 ml vials of MPA steroid for each of the patients named on the form, sometimes as many as several hundred vials in a shipment. Under Massachusetts and Maryland law the vials NECC dispensed were labeled with patients' names and were to be administered only to the patient for whom the medication was prescribed or dispensed. Dr. Bhambhani did not write patient specific prescriptions and never intended to in order to get NECC's MPA. She used the medication received on other patients (such as Brenda Rozek), and, compounding the violations (as well as the risk of multiple infections), used one 5 ml vial to draw medications for several different patients, even though the vials are for single patient use because they did not contain a preservative. This total and complete disregard for the health and safety of her patients constituted flagrant breaches of both Massachusetts and Maryland prescription laws, and governing medical standards of care. On these

¹ While Dr. Bhambhani did not use obviously made up names as other did, using the names of patients listed in past schedules on her prescriptions rather than for the intended patient was no less fake and unlawful.

factual grounds punitive damages are warranted under Maryland law as the court previously ruled when Box Hill raised the issue on Rule 12 motions.

Second, this described misconduct also violated Mass. Gen. Laws ch. 93A's consumer protection law as the conduct violated applicable and governing Massachusetts medical prescription laws. Violations of those prescription laws constitute a per se violation of Chapter 93A, and violations of Chapter 93A permit awards of punitive damages.

Box Hill Defendants request for summary judgment on Plaintiffs' punitive damages claim should therefore be denied.

II. ARGUMENT

A. Punitive Damages Are Warranted under Maryland Law.

This Court previously held that punitive damages may be maintained in this action. Dkt. No. 2225 at 7. In Maryland, "the availability of a punitive damages awards . . . depend[s] upon the heinous nature of the defendant's tortious conduct." *Owens-Illinois, Inc. v. Zenobia*, 601 A.2d 633, 650 (Md. 1992) (internal citations omitted). As this Court observed, Maryland permits punitive damages in order "to punish a party 'whose conduct is characterized by evil motive, intent to injure, or fraud . . .'" *Garcia v. Foulger Pratt Development, Inc.*, 845 A.2d 16, 46 (Md. 2003) (emphasis added) (quoting *Owens-Illinois, Inc. v. Zenobia*, 601 A.2d 633 (Md. 1992)); *see also* Dkt. No. 2225 at 7 (Sept. 9, 2015 Mem. Op.). Plaintiff has advanced facts showing Box Hill committed fraud in filling out the prescriptions by which the NECC medication was acquired that ultimately was administered to Brenda Rozek on August 30, 2012 leading to her death. *See* Ex. 1 at ¶¶ 271-275 (Plaintiffs' Complaint); *see also* Ex. 2 at 42:11-43:18; 56:25-58:5; 65:18-66:20; 108:6-109:9 (Jan. 19, 2017 Deposition of Shmuel Shoham, M.D.); Ex. 3 at 4-5 (Jan. 19, 2018

Expert Report of Lloyd Saberski, M.D.); Ex. 4 (Jan. 20, 2018 Expert Report of David R. Chason, RPh, MBA); Ex. 5 (Jan. 22, 2018 Expert Report of Shmuel Shoham, M.D.).

To establish fraud in Maryland a plaintiff must show: (1) the defendant made a false representation, while (2) either knowing the falsity of the representation or making it with reckless indifference to the truth, in order to (3) defraud the recipient (induce action or inaction or take advantage by deceit or suppression), and the recipient then (4) relies on the misrepresentation, and (5) suffers compensable injury as a result. *See Exxon Mobil Corp. v. Albright*, 433 Md. 303, 334, 71 A.3d 30, 49 (2013). Making and using false prescriptions to circumvent Massachusetts' and Maryland's prescription laws, and then administering that medication to patients other than the patients whose name is on the medication labels, such as Mrs. Rozek, is the epitome of fraud.

Although Maryland law only requires proof of reckless indifference to the truth to establish a fraud in tort, Maryland courts demand a defendant's fraudulent conduct be with "actual knowledge" to justify punitive damages. *Hoffman v. Stamper*, 385 Md. 1, 42, 867 A.2d 276, 301 (2005) (discussing Maryland jurisprudence of fraud and punitive damages). The *Hoffman* court explained "actual knowledge" is equivalent to "willful blindness to fraudulent activity." 385 Md. at 44, 867 A.2d at 302. In such an instance, a "person has his suspicion aroused but then deliberately omits to make further enquires, because he wishes to remain in ignorance." *Id.* (internal quotations and citations omitted).

The record here enables a jury to reasonably conclude that the Box Hill Defendant's fraudulent conduct justifies punitive damages under Maryland law. Dr. Bhambhani, among other things, failed to inform her patients receiving NECC preservative free MPA injections that she:

- (1) did not investigate, read any literature on, or medically analyze the risks of using preservative free MPA before incorporating it into her clinical practice; but instead, mindlessly relied on a former colleague's recommendation when deciding to purchase and administer preservative

free MPA. Ex. 6 at 101:15-102:5 (Jan. 9, 2018 Deposition of Ritu T. Bhambhani, M.D.);

- (2) purchased the preservative free MPA from a local compounding pharmacy, not a national manufacturer. *Id.* at 55:8-56:6; 61:20-62:14
- (3) failed to evaluate individual patients to determine a specific need for a compounded medication.² *Id.* at 33:12-35:9.
- (4) administered multiple doses of MPA out of the same single dose vial. *Id.* at 72:2-14; and most critically,
- (5) placed fraudulent non-patient specific prescription order forms with NECC—that is using past Box Hill clinic patients’ names—to order preservative free MPA in bulk (five, 5 ml vials per patients’ names), which doses were ultimately administered to patients whose names were not on the prescription form. *Id.* at 17:17-19:3; 38:12-40:11; 45:7-46:2; 63:17-64:18; *see also* Ex. 2 at 42:11-43:18; 56:25-58:5; 65:18-66:20; 108:6-109:9.

Cf., *Doe v. Doe*, 122 Md. App. 295, 353, 712 A.2d 132, 160 (1998) (acknowledging that the “Maryland Court of Appeals has stated that an action for fraud can stand on an omission when the relationship between the two parties imposes a duty to disclose.”); *Mole v. Jutton*, 381 Md. 27, 47, 846 A.2d 1035, 1047 (2004) (observing that a doctor in obtaining consent has a due care duty to disclose pertinent information).

Dr. Bhambhani’s utter failure to undertake the simplest of investigations about what she was injecting into her patients, and to comply with Maryland’s and Massachusetts’ law regarding prescribing, are more than just negligent shortcomings. These are all serious departures from the applicable standards of care.

And worse, here, Dr. Bhambhani’s failures and omissions were based on a “willful blindness” as she ignored red flags raised by what she described as NECC’s directing her to use

² Compounded preservative free medications should only be prescribed to patients who have had experienced negative side effects from general manufactured medications. *See* Ex. 7 at 102:11-103:6; 147:22-148:11 (January 12, 2017 Deposition of Lloyd Saberski, M.D.)

stale patient names for prescriptions. Ex. 6 at 17:17-19:3; 38:12-40:11; 45:7-46:2; 63:17-64:18. Plaintiffs' experts will prove that had she stopped and recognized that NECC was directing her to order MPA in violation of the standards of care, let alone state law, she would have seen that the ordering procedures with NECC were part of a larger fraudulent prescription scheme. *See* Exs. 3, 4, 5. Indeed, NECC's prescription order form procedures were so outrageous that Dr. Bhambhani's claim she did not believe anything was amiss stretches reality.³

The record evidence in this matter is such that Dr. Bhambhani's deceitful conduct played a very significant role in Brenda Rozek's death, conduct that was carried out with a willful blindness. Punitive damages are therefore appropriate under Maryland law, and Defendants' request for summary judgment on this issue should be denied.

B. Punitive Damages Are Warranted under Massachusetts Law.

Punitive damages are also justified under Mass. Gen. Laws ch. 93A. *See Kraft Power Corp. v. Merrill*, 981 N.E.2d 671, 684 (Mass. 2013) (observing that multiple damages authorized by Mass. Gen. Laws ch. 93A are punitive in nature, and like punitive damages in tort law, are meant to serve the twin goals of punishment and deterrence).

Chapter 93A § 9(3) allows an award of punitive damages when the defendant willfully or knowingly violated the statute. *Rhodes v. AIG Domestic Claims, Inc.*, 961 N.E.2d 1067, 1081 (Mass. 2012). Under Chapter 93A § 9 a person violates the statute if they injure a consumer by any method, act, or practice unlawful under Chapter 93A § 2. *Van Dyke v. St. Paul Fire and Marine Ins. Co.*, 448 N.E.2d 357, 360 (Mass. 1983). A defendant engages in an unlawful practice under

³ Such a claim is, at the least, a credibility determination for the jury. *Brown v. State*, 368 Md. 320, 328, 793 A.2d 561, 566 (2002) (collecting cases).

Chapter 93A § 2 by conducting deceptive acts or practices in the commission of trade, commerce, or business. Mass. Gen. Laws ch. 93A § 2(a).

By way of further explanation, the Massachusetts Attorney General Regulations declare that an act or practice of trade or commerce is in violation of Mass. Gen. Laws ch. 93A, § 2 if “[i]t fails to comply with existing statutes, rules, regulations or laws, meant for the protection of the public’s health, safety, or welfare promulgated by the Commonwealth or any political subdivision thereof intended to provide the consumers of this Commonwealth protection” 940 Mass. Code Regs. 3.16(3); *see also Klairmont v. Gainsboro Rest., Inc.*, 465 Mass. 165, 174, 987 N.E.2d 1247, 1255 (2013) (referencing and relying on 940 Mass. Regs. § 3.16 in a private civil action when analyzing Mass. Gen. Laws ch. 93A § 2(a)).

While a Massachusetts pharmacy such as NECC may legally honor and fill an out-of-state doctors’ prescription, Massachusetts’ pharmacy laws by statute govern and require the ordering, filling, and distribution of drugs comply with Massachusetts law. Mass. Gen. Laws Ch. 94C, § 18(c) (“A prescription . . . may also be issued by an authorized practitioner who is duly licensed to practice medicine and duly registered in the state wherein he resides, if required, and duly registered under federal law to write prescriptions. . . . Any prescription issued under this paragraph shall be issued in the manner prescribed in section twenty-two and all relevant provisions of this chapter shall apply to such physician and prescription.”).⁴ In addition, Massachusetts pharmacy

⁴ During oral argument on these motions Your Honor pondered why Massachusetts’ law would apply to a Maryland prescriber. As it is consistent with Maryland law, there is no conflict. More to the point, the Massachusetts’ legislature made clear that in giving out of state doctors the right to order from Massachusetts’ pharmacies, they had to comply with Massachusetts’ law.

In 2012, Mass. Gen. Laws Ch. 94C, § 22 provided that:

laws apply because pursuant to the Maryland wrongful death statute, if a wrongful death action in Maryland⁵ is based, in part, on a wrongful act that occurred outside of Maryland, that outside state's substantive law applies to that underlying conduct. Md. Code Ann., Cts. & Jud. Proc. § 3-903; *see also Jones v. Prince George's Cty.*, 378 Md. 98, 107, 835 A.2d 632, 638 (2003) (applying Virginia law in a Maryland wrongful death action to claims based on conduct that occurred in Virginia, and applying Maryland substantive law to the claims based on the conduct that occurred in Maryland).

Plaintiffs' here specifically charged and present evidence that Dr. Bhambhani and the Box Hill Defendants wrote bogus prescriptions by using past Box Hill clinic patients' names to obtain multiple 5 ml vials of MPA from NECC with the intent to administer that medication to patients other than those for which Bhambhani prescribed the medication. Ex. 1 at ¶¶ 79, 132, 271-275; *see also* Ex. 2 at 42:11-43:18; 56:25-58:5; 65:18-66:20; 108:6-109:9. This violated Massachusetts controlled substance law, which governs ordinary prescription medications, as well as DEA scheduled medications.

Flowing from her role and violation of prescription drug laws by providing false prescriptions to NECC to obtain medications for people other than her patients whose names she

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- (a) A practitioner who dispenses a controlled substance by issuing a written prescription shall state on the prescription the name, address and registration number of the practitioner, the date of delivery of the prescription, the name, dosage and strength per dosage unit of the controlled substance, *the name and address of the patient unless it is a veterinary prescription*, the directions for use and any cautionary statements required, and a statement indicating the number of times to be refilled.

Mass. Gen. Laws ch. 94C, § 22 (emphasis added).

⁵ Plaintiffs here asserted claims for all allowable damages under Maryland's wrongful death law for the loss of Brenda L. Rozek. Ex. 1 at ¶ 310.

wrote on the prescription forms, Plaintiffs' contend that the Box Hill Defendants both directly violated Chapter 93A and, as well, aided and abetted⁶ NECC's violation of it, by dispensing fraudulent and misbranded MPA vials in violation of Massachusetts law. These violations resulted in the illegal dispensing and delivery of contaminated NECC preservative free MPA to Box Hill in Maryland, which Dr. Bhambhani in turn injected into Brenda Rozek, fatally injuring her. *See* Ex. 1 at ¶¶ 271-275; *see also* Ex. 2 at 42:11-43:18; 56:25-58:5; 65:18-66:20; 108:6-109:9; Ex. 3 at 4-5; Ex. 4; Ex. 5.

Dr. Bhambhani and the Box Hill Defendants thus either directly, or by way of aiding and abetting NECC, violated Chapter 94C § 22, and in turn, engaged in an unlawful and deceptive business practice under Chapter 93A § 2(a). Punitive damages are therefore appropriate under Chapter 93A § 9(3).

III. CONCLUSION

For all the foregoing reasons, Plaintiffs respectfully request that this Court deny the Box Hill Defendants' Motion for Summary Judgement regarding Plaintiffs' claim for punitive damages.

⁶ The Massachusetts Supreme Judicial Court has recognized aiding and abetting as a theory of liability. *McIntyre v. United States*, 447 F. Supp. 2d 54, 105 n.91 (D. Mass. 2006) (citing *Davis v. United States*, 340 F. Supp. 2d 79, 91 (D. Mass. 2004)).

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Michael Coren, hereby certify that a copy of the foregoing document, filed through the CM/ECF system will be accessible to those attorneys who are registered with the Court's electronic filing system and Notice of Electronic filing (NEF), including the attorneys representing the defendants in the above-referenced individual cases, and will be sent to these parties by operation of the CM/ECF system.

/s/ Michael Coren

Michael Coren

Dated: February 2, 2018